Dated this 15<sup>th</sup> day of November 2002

**ENCORET LIMITED** 

to

ATROPOS LIMITED

**ASSIGNMENT OF INTELLECTUAL PROPERTY** 

### THIS ASSIGNMENT is dated 15th November 2002 and is made between

- (1) Encoret Limited whose registered office is at 40 Lower Baggot Street, Dublin 2 (the "Assignor") and
- (2) Atropos Limited whose registered office is at Unit 4, Sunnybank Centre, Bray, County Wicklow (the "Assignee").

#### RECITALS

- A. By an agreement made between a number of parties including the Assignor and the Assignee on 2<sup>nd</sup> October 2002 the Assignor agreed to assign certain intellectual property rights to the Assignee.
- B. The Assignor wishes to assign additional Intellectual Property Rights (hereinafter defined) to the Assignee for the consideration set out in this Assignment.

#### IT IS HEREBY AGREED as follows:

#### 1 INTERPRETATION:

- 1.1 Headings are inserted for convenience only and do not affect the construction of this Assignment.
- 1.2 Unless the context otherwise requires, words importing the singular include the plural and vice versa, words importing the masculine include the feminine, and words importing persons include corporations.
- 1.3 Reference in this Assignment to writing or similar expressions includes, where the context so admits, transmission by facsimile, e-mail or comparable means of communication.
- 1.4 Reference in this Assignment to "Applications" means all or any of the applications for patents set out in Schedule 1.
- 1.5 References in this Assignment to "Patents" means all or any of the patents set out in Schedule 1.
- 1.6 References in this Assignment to "Intellectual Property Rights" means the Applications and the Patents.

#### 2 ASSIGNMENT:

Subject as hereinafter provided the Assignor HEREBY GRANTS, ASSIGNS AND TRANSFERS absolutely and exclusively to the Assignee, and free from all liens, charges and encumbrances, all of its rights, title and interest of whatsoever nature in the Intellectual Property Rights together with all rights and powers arising or accrued therefrom including the right to sue for damages and other remedies in respect of any infringements of the Intellectual Property Rights or other acts within the scope of the claims of any public specification of any of the Patents or accompanying any Application prior to the date hereof and the right to apply for, prosecute and obtain patent or similar protection throughout the world in respect of the inventions claimed in the Patents and the Applications including the right to claim priority therefrom to the extent that the grant of any patents or similar protection shall be in the name of and vest in the Assignee.

#### 3 CONSIDERATION

- 3.1 The Assignee undertakes to pay the Assignor on the grant of any patent based on the Intellectual Property Rights assigned the following consideration:
  - 3.1.1 A three percent (3%) royalty based upon the gross proceeds received by Assignee from:
    - (a) the sale by Assignee, or licensee of Assignee, of commercialised products which are covered within a particular patent jurisdiction by any granted patent issuing from any of the Applications listed on Schedule 1 (hereinafter "Royalty-Bearing Patent") pertaining to said Royalty-Bearing Patent; and
    - (b) the sale of the subject Intellectual Property Rights herein;
    - (c) provided, however, that such royalty payment shall be limited in the aggregate amount to a royalty cap of Euro 250,000, at which time the royalty obligations hereunder shall be deemed fully paid-up.
  - 3.1.2 A minimum royalty payment of Euro 50,000, to be paid within three (3) years from the date of execution of this agreement, which shall be included toward satisfying the above-mentioned royalty cap.
- 3.2 The Assignee shall within twelve (12) months of the date of this Assignment confirm whether it intends to apply for patents for the Intellectual Property Rights

and in the event the Assignee decides not to apply for or not to process patent applications which it has commenced for the Intellectual Property Rights it shall for the consideration of One Euro GRANT, ASSIGN AND TRANSFER absolutely and exclusively to the Assignor, and free from all liens, charges and encumbrances, all of its rights, title and interest of whatsoever nature in the Intellectual Property Rights together with all rights and powers arising or accrued therefrom including the right to sue for damages and other remedies in respect of any infringements of the Intellectual Property Rights or other acts within the scope of the claims of any public specification of any of the Patents or accompanying any Application prior to the date hereof and the right to apply for, prosecute and obtain patent or similar protection throughout the world in respect of the inventions claimed in the Patents and the Applications including the right to claim priority therefrom to the extent that the grant of any patents or similar protection shall be in the name of and vest in the Assignor.

#### 4 WARRANTIES:

The Assignor hereby warrants that:

4.1 the Assignor is entitled to enter into this Assignment and to grant, assign and transfer to the Assignee all the rights herein expressed to be granted, assigned and transferred to the Assignee;

the Intellectual Property Rights contain nothing that is libellous, defamatory or indecent,

#### 5 FURTHER ACTS AND ASSURANCES:

The Assignor shall, at the request and expense of the Assignee, do all acts and execute, or procure that there shall be done and executed, all documents, instruments, matters, acts and things which may be necessary or desirable to confirm the title of the Assignee to the Intellectual Property Rights hereby assigned or to give effect thereto, whether in connection with any registration of such title or otherwise, and to effect fully the purposes, terms and conditions of this Assignment. The Assignor hereby irrevocable appoints each of the directors from time to time of the Assignee as its attorney in its name and on its behalf to

execute and do any such instruments or things and to use its name in each case for the purpose only of giving to the Assignee or its nominees the full benefit of the provisions of this clause and for no other purpose whatsoever.

- 5.2 Subject to reservations of Section 3.2 above, the Assignee shall, at the request and expense of the Assignor, do all acts and execute, or procure that there shall be done and executed, all documents, instruments, matters, acts and things which may be necessary or desirable to reconfirm the title of the Assignor to the Intellectual Property Rights hereby assigned or to give effect thereto, whether in connection with any registration of such title or otherwise, and to effect fully the purposes, terms and conditions of the reassignment. The Assignee hereby irrevocable appoints each of the directors from time to time of the Assignor as its attorney in its name and on its behalf to execute and do any such instruments or things and to use its name in each case for the purpose only of giving to the Assignor or its nominees the full benefit of the provisions of this clause and for no other purpose whatsoever.
- 5.3 The Assignor and the Assignee agree that in the event that either party believes that it may have a claim or right of action against the other, arising out of this Assignment of the Intellectual Property Rights, the managing directors (or other designated representatives) of the Assignor and Assignee will, prior to asserting any such claim or right or commencing any action in respect thereof, enter into good faith discussions for a period of ninety (90) days for the purpose of attempting to resolve any dispute between the parties, but without prejudice to each party's entitlement to rely upon its legal remedies, or assert its rights in law.

#### 6 INDEMNITY:

Each party (the "Indemnifying Party") shall indemnify, and keep the other party (the ("Indemnified Party") fully and effectually indemnified, against all and any loss, damages, costs, expenses and liabilities of whatsoever nature sustained or incurred by the Indemnified Party directly or indirectly and howsoever arising (including reasonable legal fees, costs and expenses) in consequence of any breach, non-performance or non-observance by the Indemnifying Party of any of the agreements, conditions, obligations, representations, warranties and undertakings on the part of the Indemnifying Party contained in this Assignment, and the Indemnifying Party shall provide all such reasonable assistance as the Indemnified Party may from time to time request to enable

it to resist any action, claim or proceedings brought against it as a consequence of any such breach.

## 7 GENERAL:

This Assignment will be governed by and construed in accordance with the laws of Ireland, and the Irish courts will have exclusive jurisdiction in respect of it.

IN WITNESS whereof the Assignor and the Assignee have caused this Assignment to be duly executed on the date first herein written.

# SCHEDULE 1

# Intellectual Property Rights

Patents or patent applications as follows:

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Appln. No.TerritoryAppln. DateStatusUSSN 08/513,986United States6 September 1994

UNITED STATES DEPARTMENT OF COMMERCE

Patent and Trademark Office

OF PATENTS AND TRADEMARKS Washington, D.C. 20231

ASSISTANT SECRETARY AND COMMISSIONER

JUN 2 0 20**03** 

MAY 23, 1997

SIXBEY, FRIEDMAN, LEEDOM & FERGUSON, P.C., DANIEL W. SIXBEY 2010 CORPORATE RIDGE, SUITE 600 MCLEAN, VA 22102

### UNITED STATES PATENT AND TRADEMARK OFFICE NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS AVAILABLE AT THE ASSIGNMENT SEARCH ROOM ON THE REEL AND FRAME NUMBER REFERENCED BELOW.

PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE INFORMATION CONTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA PRESENT IN THE PATENT AND TRADEMARK ASSIGNMENT SYSTEM. IF YOU SHOULD FIND ANY ERRORS OR HAVE QUESTIONS CONCERNING THIS NOTICE, YOU MAY CONTACT THE EMPLOYEE WHOSE NAME APPEARS ON THIS NOTICE AT 703-308-9723. PLEASE SEND REQUEST FOR CORRECTION TO: U.S. PATENT AND TRADEMARK OFFICE, ASSIGNMENT DIVISION, BOX ASSIGNMENTS, NORTH TOWER BUILDING, SUITE 10C35, WASHINGTON, D.C. 20231.

RECORDATION DATE: 02/02/1996

REEL/FRAME: 8437/0428

NUMBER OF PAGES: 2

BRIEF: ASSIGNMENT OF ASSIGNOR'S INTEREST (SEE DOCUMENT FOR DETAILS).

ASSIGNOR:

BONADIO, FRANK

DOC DATE: 07/25/1995

ASSIGNEE:

ENCORET LIMITED, AN IRISH COMPANY 17 DAME STREET DUBLIN 2, IRAN

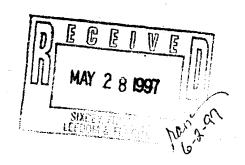
SERIAL NUMBER: 08641811

PATENT NUMBER:

FILING DATE: 05/02/1996

ISSUE DATE:

KIMBERLY BARNES, EXAMINER ASSIGNMENT DIVISION OFFICE OF PUBLIC RECORDS



04-14-1997



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1.	Name of conveying party(ies): Frank Bonadio	ř		
Add	ditional name(s) of conveying party(ies) attached? Yes _X No			•
2.	Name and address of receiving party(ies):			
Nan	ne: ENCORET LIMITED, an Irish company		. ·	·
	eet Address: 17 Dame Street			
	y Dublin 2 County	Country _	Ireland	
Add	ditional name(s) & addresses(es) attached?Yes _X_ No			
<b>3</b> .	Name of Conveyance:			
•	X Assignment Merger		· '	
	Security Agreement Change of Name		· ·	
	Other Execution Date:July 25, 1995			
	A lication week or (a) or motion to number (a).			
4.	Application number(s) or patent number(s):			
	If this document is being filed together with a new application, the execution	date of the app	plication is:	·
Title	APPARATUS FOR USE IN SURGERY AND A VALVE			
	Patent Application No.(s)  B. Patent No.(s)			
	Additional numbers attached? Yes	X No		
5.	Name and address of party to whom correspondence concerning document sh	ould be mailed	:	
	Name: Daniel W. Sixbey, SIXBEY, FRIEDMAN, LEEDOM & FERGUSO	N PC		
	Street Address: 2010 Corporate Ridge, Suite 600	11, 1.0.	·	<del></del>
	City: McLean State: Virginia	ZIP 22102		
6.	Total number of applications and patents involved: _1_			
7.	Total fee (37 CFR 3.41):			
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9.	Statement and signature.			
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	ne of Person Signing  Signature  All number of pages comprising cover sheet, attachments and document: 2	, D	Date / /	

# GNMENT OF PATENT APPLE TION

WHEREAS, FRA	NK B	ONADIO	a citizen of	Ut	nited States of A	merica :
residing at 2 Martel	lo T	errace, Bray, Count	y Wicklow, I	rela	and	
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ASSIGNOR(S), is/are the	inven	tor(s) of an invention in	APPARATUS	FOR	USE IN SURGERY A	ND A VALVE
or which I/we have execu	ted a	n application for Letters	Patent of the U	Juite	States,	
•	LZI.	of even date herewith				
(Cneck One)						
		serial numberfiled	<del></del>			
WHEREAS, ENCO	RET	LIMITED, an Irish	company, of	2	Martello Terrace,	Bray, Count
اندند. Wicklow, Ireland	ignes	C:c i zensa ip	Corporate Situs		Agaress	
SSIGNEE, is desirous of	obta	ring the entire right title	and interest in	L to	and under the said in	vention and the
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ne said invention, and the atent of the United States are took and I/we hereby a etters Patent for said invescordance with the terms	which thori ntion	ch may be granted therefore and request the Communication to the said ASSIGNEE,	on and all reexa missioner of Pat	mina ents	tion certificates, reissur of the United States,	es and extension to issue all
	Y co	venant that I/we have the	full right to co	onvey coni	the entire interest he	rein assigned,
AND I/WE HEREB ccessors, legal represental gal proceeding, sign all laths and generally do ever signs, to obtain and enfor	ives : wful ythin	papers, execute all divisions papers, execute all divisions page 2 possible to aid the said	own to me/us re onal, continuing ASSIGNEE, it	spec and s suc	ring said invention, and reissue applications, m cessors, legal represen	d testify in any take all rightful tatives and
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### UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Offic

ASSISTANT SECRETARY AND COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

Sixbey, Friedman, Leedom & Ferguson, P.C. Suite 600

2010 Corporate Ridge McClean, VA 22102

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In re Application of

Bonadio and Reid Application No. 08/641,811

Filed: May 1, 1996

For: Apparatus for Use In

Surgery and a Valve

: DECISION ACCORDING STATUS

: UNDER 37 CFR 1.47(a)

This is in response to the "Renewed Petition Pursuant to 37 CFR 1.47," filed May 2, 1996.

The petition sets forth the last known address of Alan Reid and states that Mr. Reid has refused to execute the declaration. Included with the petition is a copy of a letter to Mr. Bonadio from Mr. Reid in which Mr. Reid states that he is not willing to sign the declaration and requesting that Mr. Bonadio stop corresponding with him on the matter.

On November 6, 1996, a supplemental response was filed. supplemental response includes:

- (1) a declaration of facts of Frank Bonadio (with attachments); and
- (2) an affidavit of facts of Martin Caldwell stating that as recently as July 1, 1996 he communicated with Mr. Reid regarding the application papers and that he sent the "relevant correspondence" to Mr. Reid requesting that he reconsider his position.

The above-identified application and papers have been reviewed and found in compliance with 37 CFR 1.47(a). It is reasonable to conclude from Mr. Reid's statements and from his failure to provide an executed oath or declaration that he has refused to join in the application.

This application is hereby accorded Rule 1.47(a) status and Application Branch is authorized to:

- (1) accept this application under Rule 1.47(a);
- (2) process the application with the inventors being Bonadio and Reid, using the Declaration filed on May 1, 1996; and

(3) mail a filing receipt with a filing date of May 1, 1996.

As provided in Rule 1.47(a), this Office will forward notice of this application's filing to non-signing inventor Reid at the address given in the Declaration. Notice of the filing of this application will also be published in the Official Gazette.

Inquiries regarding this decision should be directed to the undersigned at (703) 306-3159.

Karin Tyson Legal Advisor

Special Program Law Office

Office of the Deputy Assistant Commissioner

for Patent Policy and Projects

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on December 16, 1997.

Susan Y. Stiles

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JUN 2 0 3003

Docket: 1890-5

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT application of	)
Frank BONADIO et al.	
Serial No. 08/641,811	) Art Unit: 3301
Filed: May 2, 1996	) Examiner R. Racunas
For: APPARATUS FOR USE IN	),
SURGERY AND A VALVE	) Date: December 16, 100

## **AMENDMENT**

Honorable Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

In response to the Office Action dated July 23, 1997, please amend the above entitled application as follows:

# In the Specification:

Page 8, line 12, after "cover" delete ---11--- and add ---12---. line 12, after "flange" delete ---12--- and add ---11---.

After page 14 on a separate sheet as page 15, add

# <u>ABSTRACT</u>

Apparatus for use in surgery which includes a sleeve having an entry opening at an outer end thereof and an exit opening at an inner end thereof to access a patient's body. An exit sealing unit is provided for sealing the exit opening to the patient's body and

an entry sealing unit is provided for sealing an outer entry opening against an arm passing therethrough to create a controlled environment within the sleeve. The entry sealing unit includes two spaced rings joined by a flexible tube which are twisted and locked to create a seal.---

## In the Claims:

Claim 5, line 1, after "claim" delete ---4--- and add ---26---.

line 3, after "exit" add ---opening---.

Claim 9, line 1, after "claim" delete ---1--- and add ---26---.

Claim 10, line 3, after "allow" delete ---an arm--- and add ---a forearm---.

line 4, after "against the" delete ---arm--- and add ---forearm---.

Claim 17, line 1, after "claim" delete ---1--- and add ---26---.
line 4, after "has" delete ---an arm--- and add ---a surgeon's forearm---.

Please cancel claims 1-4, 7, 11-16 and 18-24 and add claims 25-61 as follows:

---25. Apparatus for use in surgery for receiving the hand and forearm of a surgeon to provide an entry to a patient's body through an incision made in the patient's skin comprising:

an elongate sleeve having an entry opening at an outer end of said sleeve and an exit opening at an inner end of said sleeve spaced from said entry opening to provide access through said incision to the patient's body, said entry opening being positioned by said elongate sleeve in spaced relationship away from said incision when said exit opening is positioned to provide access through said incision, said sleeve being formed with flexible, bendable outer walls of a gas impervious, flexible sheet material, said outer walls including a sleeve sidewall to define an elongate passage between said entry and exit openings to receive a surgeon's hand and forearm, and exit sealing means formed on said sleeve for engaging and sealing against the patient's skin externally of the patient's body to seal said exit opening to the patient's body around said incision, said sleeve being dimensioned to extend for a distance away from said exit opening sufficient to permit the sleeve side wall to surround a portion of a surgeon's forearm spaced above the surgeon's wrist before the surgeon's hand has passed through said exit opening, and entry sealing means formed on said sleeve adjacent said entry opening for sealing the sleeve into engagement against a surgeon's forearm in spaced relation to the surgeon's wrist to create a controlled environment within said sleeve, the flexible, bendable sidewall of said sleeve surrounding the surgeon's forearm below the entry sealing means permitting free movement of the forearm laterally relative to the patient's body and longitudinally toward the patient's body.

- 26. Apparatus as claimed in claim 25 wherein said sleeve is closed at the inner end thereof to close said elongate passage, said exit opening being formed in the sidewall of said sleeve adjacent the closed inner end thereof to communicate with said elongate passage; said sleeve extending laterally from said exit opening to said entry opening.
- 27. The apparatus as claimed in claim 26 which includes an internal sealing means formed on said sleeve within said passage between said entry and exit sealing means to seal said passage, said internal sealing means forming a normally closed aperture which opens to permit passage of an object through said passage from the entry opening toward said exit opening.
- 28. Apparatus as claimed in claim 9 wherein said valve means includes first and second spaced flanges, at least one of which is secured to said elongate sleeve adjacent said entry opening and a tube of flexible material connected between said first and second flanges, said flanges being relatively movable to twist said tube into engagement with an object.
- 29. Apparatus as claimed in claim 28 wherein locking means are provided on said first and second flanges for releasably locking said first and second flanges together.
- 30. The apparatus as claimed in claim 29 which includes an internal sealing means formed on said sleeve within said passage between said entry and exit sealing means to seal said passage, said internal sealing means forming a normally closed aperture which opens to permit passage of an object

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through said passage from the entry opening toward said exit opening.

- 31. Apparatus as claimed in claim 9 wherein said entry sealing means includes a first flange secured to said sleeve at said entry opening, a surgical glove having a glove open end for receiving a surgeon's hand, a second flange secured to said surgical glove at said glove open end, said second flange engaging said first flange to close and seal the entry opening of said sleeve when said glove has passed through said entry opening.
- 32. Apparatus for use in minimally invasive surgery through a wound into an insufflated cavity, comprising:

an outer sleeve of gas-impermeable supple material having an entry opening at a proximal end thereof and an exit opening at a distal end thereof;

first sealing means adapted to seal the exit opening gastightly around the wound in a patient; and

second sealing means adapted to seal the entry opening gastightly around a surgeon's arm received therein and create thereby a gastight chamber in said outer sleeve when a surgeon's arm is operatively received in said sleeve;

whereby the sleeve cooperates with the first and second sealing means to enable the surgery to be performed under insufflatable conditions.

# 33. Apparatus according to claim 32 further comprising:

third sealing means interposed in said sleeve between said first and second sealing means adapted to maintain the gastight chamber with the wound when said second sealing means is breached.

## 34. Apparatus according to claim 33 wherein:

said third sealing means includes an inner sleeve having a proximal end sealingly joined at facing portions to said outer sleeve and a distal end forming a normally closed aperture which opens automatically in response to movement of an object from proximal to distal locations therethrough.

# 35. Apparatus according to claim 32 wherein:

said first sealing means includes a flexible flange secured around said exit opening and having an exposed face adapted to attach around the wound.

- 36. Apparatus according to claim 35 further comprising: an adhesive coating on said exposed face adapted to adhere to said flange around the wound.
  - 37. Apparatus according to claim 36 further comprising: a peel-off strip covering said adhesive coating.
  - 38. Apparatus according to claim 32 wherein:

said entry and exit openings are formed to accommodate a surgeon's hand and forearm.

39. Apparatus according to claim 32 wherein:

said entry and exit openings are formed to accommodate instrumentarium.

40. Apparatus according to claim 32 wherein:

said material is sufficiently flexible for effecting a wide range of arm movement at said entry opening relative to said exit opening.

# 41. Apparatus according to claim 32 further comprising:

a wound protector means adapted to be inserted in the wound for simultaneously lining said exit opening and the wound, said protector including a pair of generally coaxial resilient rings contiguously connected to respective ends of a flexible tube, one of said rings being formed to compress said tube within said outer sleeve around said exit opening and the other of said rings adapted to compress said tube around the internal side of the wound.

- 42. Apparatus according to claim 41 wherein said tube is made of a supple material effectively impermeable to gases and microorganism-bearing fluids.
  - 43. Apparatus according to claim 42 wherein; said tube is adapted to be in contiguous contact with the wound.
  - 44. Apparatus according to claim 32 wherein:

said second sealing means includes a pair of flanges interconnected on a common axis by a supple tube, said flanges being relatively adjustable about said axis for twisting said tube into a constricting position around an object.

45. Apparatus according to claim 44 wherein:

said flanges include means for locking said flanges together in the constricting position.

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# 46. Apparatus according to claim 32 wherein:

said second sealing means includes a first flange secured around said entry opening, a surgical glove for inserting into said outer sleeve through said first flange, and a second flange secured around the opening of said glove for sealing attachment to said first flange.

47. Apparatus for use in hand-assisted minimally-invasive surgery in a sufflatable body cavity having an outer surface, comprising:

an elongate flexible sleeve having an end portion adapted to be positioned adjacent the body cavity and a proximal end portion adapted to be positioned away from the body;

means defining an exit opening laterally of said flexible sleeve adjacent to said distal end portion;

means defining an entry opening coaxially of said flexible sleeve at said proximal end portion;

first sealing means carried by said sleeve and surrounding said exit opening and adapted to engage said body outer surface;

second sealing means carried by said sleeve and surrounding said proximal end portion adapted to seal gastightly a surgeon's arm; and

means in said sleeve between its distal and proximal end portions providing a normally-closed flexible valve adapted to open upon insertion of the surgeon's hand toward the distal end portion of the sleeve and automatically close gastightly upon withdrawal of the surgeon's hand, said valve providing a third sealing means cooperable with said first sealing means to define a substantially gastight chamber in communication with said exit opening;

whereby the surgeon can readily insert and withdraw the hand from the body cavity in the course of surgery without significant loss of pressure in the body cavity when sufflated.

- 48. Apparatus according to claim 47 wherein said normally closed valve is of the duckbill type formed by at least one flexible panel secured to said sleeve and providing an aperture at a location adjacent to said exit opening.
- 49. Apparatus according to claim 47 wherein said means defining an exit opening includes an annular flange having an adhesive coating adapted to secure the sleeve to the body outer surface with the sleeve extending alongside the body.
- 50. Apparatus according to claim 47 including a flexible, tubular wound protector depending from said means providing said exit opening adapted to be inserted into a wound formed in said outer surface, said wound protector including a flexible membrane mounting annular elastic rings at opposite ends.
- 51. Apparatus according to claim 47 wherein said proximal end second sealing means is adapted to engage gastightly the periphery of the surgeon's arm when the hand is inserted in the sleeve.
- 52. Apparatus for use in hand-assisted minimally invasive surgery in a gas sufflatable body, comprising:

an elongate flexible sleeve having a lateral exit opening at one location and an axial entry opening at another location;

first means adapted to seal gastightly said sleeve around said exit opening to a body surface undergoing minimally invasive surgery;

second means adapted to seal gastightly said sleeve around a surgeon's arm adjacent to said entry opening; and

means providing a duckbill check valve in said sleeve for preventing gas flow from said exit opening to said entry opening when said second sealing means is unsealed;

whereby a surgeon may insert and withdraw the hand through the exit opening without significantly affecting gas pressure in the sufflated body.

53. Surgical apparatus for use in minimally invasive surgery for introducing a hand or instrument through a wound into an insufflated cavity comprising:

protective sleeve means of gas-impermeable material having a distal end adapted to be inserted through the wound for overlapping the lower edge thereof, and a proximal end formed to extend out of the wound;

an inside sealing ring, operatively connected to said sleeve means in proximity to the distal end, adapted to self-seal gastightly around the inside of the wound;

an outside sealing ring, operatively connected to said protective sleeve means in proximity to the proximal end thereof and forming with said first sealing means a gastight chamber in said protective sleeve means and adapted to seal gastightly around the outside of the wound;

an elongate gas-impermeable supple sleeve extending laterally of said

outside sealing ring; and

means providing a gastight-seal on said elongate sleeve at an end thereof remote from said outside sealing ring;

whereby the wound is protected by the protective sleeve while insufflation gas is contained within the elongate sleeve.

- 54. Surgical apparatus according to claim 53 wherein: said sleeve means includes a tubular portion closely conforming to the wound surface.
- 55. Surgical apparatus according to claim 53 wherein: said first sealing means includes a normally closed resilient member formed to prevent gas flow from the cavity into the chamber.
- 56. Surgical apparatus according to claim 53 further comprising: a resilient ring affixed around the distal end and adapted to expand beyond the edge of the wound when the distal end is fully inserted in the wound.
- 57. Apparatus for use in surgery for receiving the hand of a surgeon to provide an entry to a patient's body through an incision made in the patient's skin comprising:

a sleeve having an entry opening at a first end thereof and an exit opening at a second end thereof spaced from said first end, said sleeve being formed to define an enclosed sleeve passage between said entry and exit openings,

exit sealing means formed on said sleeve to seal said sleeve at the exit opening to the patient's body around said incision, and

a glove assembly having an open end to permit passage into the glove assembly of a surgeon's hand, said glove assembly and sleeve being formed to permit attachment of said glove assembly to said sleeve to close and seal said sleeve passage in the area of said entry opening while permitting passage of a surgeon's hand in said glove through the exit opening into a patient's body through the incision, said glove assembly being formed to receive a surgeon's hand and to extend over a surgeon's wrist and forearm.

- 58. Apparatus as claimed in claim 57 wherein said exit sealing means includes a flexible flange secured to said sleeve and extending around said exit opening, said flange having an exposed face adapted to attach around the incision.
- 59. Apparatus according to claim 58 wherein said glove member is attached to said sleeve adjacent to the open end of said glove member.
- 60. Apparatus according to claim 59 which includes a first connector formed at the entry end of said sleeve and a second connector formed adjacent to the open end of said glove assembly, said first and second connectors cooperating to connect and seal said glove assembly to said sleeve.
- 61. Apparatus according to claim 60 wherein said first connector includes a first flange formed on said sleeve around said entry opening and said second connector includes a second flange formed on said glove assembly

around the open end of said glove assembly, said first and second flanges including means for locking said first and second flanges together.---

## **REMARKS**

Claims 32-56 have been added to initiate an interference with U.S. Patent No. 5,640,977 ('977) to Leahy et al. Claims 32-34 correspond to claims 1-3 of the '977 patent, claims 35-43 correspond to claims 5-13 of the '977 patent, claims 44-48 correspond to claims 17-21 of the '977 patent and claims 49-56 correspond to claims 24-31 of the '977 patent. Applicants' application is entitled to priority based on Irish application nos. 930649 and 930650 filed September 6, 1993, and PCT application No. PCT/IE94/00045 filed September 6, 1994. Thus applicants' application predates the earliest priority date of April 8, 1994, for the '977 patent.

On the attached sheets, Appendices A and B respectively, Applicants have indicated where the copied claims 32-56 find support in Applicants' specification and drawings, and the counts which cover both the Patentees' and the Applicants' claims. In Appendix C, applicants show where the counts are supported by applicants' specification and drawings. In Appendix D applicants have indicated where copied claims find support in Irish priority document number 930649.

It is important to note that certain figures of drawing in U.S. Patent No. 5,640,977, with the exception of reference numerals, are substantially identical to figures of drawing in applicants' application and applicants' priority applications PCT/IE94/00045 and Irish applications numbers 930649 and 930650. Figures 13, 14 and 15 of the patent are substantially identical to Figures 1, 2 and 3 respectively of applicants' application and PCT and Irish

(930649) priority documents, Figure 17 of the patent is substantially identical to Figure 4 of applicants' application and Irish (930649) and PCT priority documents. Figures 16A, 16B and 16C of the patent are substantially identical to Figures 5, 6 and 7 respectively of applicants' application and the PCT and Irish (930649) priority documents, and Figures 18 and 19 of the patent are substantially identical to Figures 8 and 9 of applicants' application and PCT and Irish (930649) priority documents.

The abstract has been added by amendment and a separate numbered page containing the abstract is submitted herewith.

Claims 1-4, 7, 11-16 and 18-24 have been hereby cancelled thereby eliminating claims rejected under 35 USC 112. These claims have been replaced by claims 25-31 and 57-61 which meet the requirements of 35 USC 112 and distinguish applicants' invention from the references of record.

Claim 25, and claims 5, 6, 8, 9, 17 and 26-31 which are dependent thereon distinguish applicants' invention from any reference of record or combination thereof. These claims define an elongate sleeve having an entry opening adapted to be spaced away from an incision when the sleeve exit opening is positioned to provide access to the incision. This permits the sleeve to seal against a surgeon's forearm in spaced relation to the surgeon's wrist before the surgeon's hand has passed through the incision. Thus these claims define an elongate flexible sleeve extending for a substantial distance away from an incision when the sleeve is sealed around the incision to permit the sleeve to create a controlled environment around the surgeon's hand, wrist and forearm before the hand enters the incision. The flexible sleeve permits the hand to move forward into the incision and the forearm to move universally around the incision. No reference of record shows these features.

In the Brinkerhoff et al. device, the entry to the sleeve is the entry to the incision and the sleeve does not extend outwardly from a seal externally of the patient's body.

Claim 57 and claims 58-61 which are dependent thereon define a structure not disclosed by the references of record taken singly or in combination. No reference discloses attaching a glove assembly to a sleeve through which it passes so that the glove assembly can exit the sleeve to which it is attached through an exit opening in the sleeve. This requires a long glove assembly which extends over a surgeon's wrist and forearm and which is formed to permit attachment in the area of the open end of the glove assembly to the sleeve in the area of an entry opening in the sleeve to close and seal the sleeve passage at the entry opening. No reference discloses a glove secured to a sleeve in this manner.

Claims 32-56 have previously been found to be allowable by the Patent and Trademark Office in the '977 patent.

For the above reasons, allowance of claims 5, 6, 8, 9, 10, 17, 25-31 and 57-61 is respectfully requested and it is requested that an interference with U.S. Patent No. 5,640,977 be instituted.

Respectfully submitted,

Daniel W. Sixbey Reg. No. 20,932

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# **ABSTRACT**

Apparatus for use in surgery which includes a sleeve having an entry opening at an outer end thereof and an exit opening at an inner end thereof to access a patient's body. An exit sealing unit is provided for sealing the exit opening to the patient's body and an entry sealing unit is provided for sealing an outer entry opening against an arm passing therethrough to create a controlled environment within the sleeve. The entry sealing unit includes two spaced rings joined by a flexible tube which are twisted and locked to create a seal.

5

## APPENDIX A - COPIED CLAIMS

### PATENT CLAIM

1. 32. Apparatus for use in minimally invasive surgery through a wound into an insufflated cavity, comprising:

an outer sleeve of gas-impermeable supple material having an entry opening at a proximal end thereof and an exit opening at a distal end thereof;

first sealing means adapted to seal the exit opening gastightly around the wound in a patient; and

second sealing means adapted to seal the entry opening gastightly around a surgeon's arm received therein and create thereby a gastight chamber in said outer sleeve when a surgeon's arm is operatively received in said sleeve;

whereby the sleeve cooperates with the first and second sealing means to enable the surgery to be performed under insufflatable conditions.

2. 33. Apparatus according to claim 32 further comprising:

third sealing means interposed in said sleeve between said first and second sealing means adapted to maintain the gastight chamber with the wound when said second sealing means is breached.

3. 34. Apparatus according to claim 33 wherein:

said third sealing means includes an inner sleeve having a proximal end sealingly joined at facing portions to said outer sleeve and a distal end forming a normally closed aperture which opens automatically in response to movement of an object from proximal to distal locations therethrough.

# SUPPORT IN APPLICATION AND PCT PRIORITY DOCUMENT

Page 1, lines 1-5; Apparatus 1 Page 7, lines 1-4; Figs. 1 and 3.

Page 2, lines 5-17; sleeve 2 Page 7, lines 4-6; Entry opening 4 Page 7, lines 7-9; Exit opening 5 Page 7, lines 9-13; Figs. 1, 3, 9.

Exit sealing means 10-11 Page 7, lines 14-19; Figs. 1, 2, 3, 4; Ring 61, diaphragm 62 and inner ring 63 Page 9, lines 27-33, Page 10, lines 1-4 Fig. 9.

Valve means 20 Page 7, lines 20-33, Page 8, lines 1-10, Figs. 3-7; First ring 51, second ring 52 and glove 53, Page 9, lines 20-26 Fig. 8.

Page 8, lines 28-34.

Valve 74 Page 10 lines 10-13, Page 11 lines 12-17; Fig. 10.

Valve 74 Page 10 lines 23-26; Page 11 lines 12-17; Fig. 10.

5. 35. Apparatus according to claim 32 wherein:

said first sealing means includes a flexible flange secured around said exit opening and having an exposed face adapted to attach around the wound.

6. 36. Apparatus according to claim 35 further comprising:

an adhesive coating on said exposed face adapted to adhere to said flange around the wound.

- 7. 37. Apparatus according to claim 36 further comprising:
  - a peel-off strip covering said adhesive coating.
- 8. 38. Apparatus according to claim 32 wherein:

said entry and exit openings are formed to accommodate a surgeon's hand and forearm.

9. 39. Apparatus according to claim 32 wherein:

said entry and exit openings are formed to accommodate instrumentarium.

10. 40. Apparatus according to claim 32 wherein:

said material is sufficiently flexible for effecting a wide range of arm movement at said entry opening relative to said exit opening.

# SUPPORT IN APPLICATION AND PCT PRIORITY DOCUMENT

Flange 11 Page 7, lines 14-19; Figs. 1-4; Page 8, lines 11-15; Flange 72, Page 10, lines 21-23; Fig. 10.

Page 7, lines 14-19; Page 11, lines 3-6.

Peel off cover 12; Page 7, lines 18-19; Fig. 2, Page 2, lines 24-25.

Page 7, lines 5-9; Page 8, lines 16-20; Page 11, lines 8-15 Fig. 4.

Page 7, lines 5-9.

Page 7, lines 4-5; Page 10, lines 5-9 and 18-20; Page 18, lines 6-12.

11. 41. Apparatus according to claim 32 further comprising:

a wound protector means adapted to be inserted in the wound for simultaneously lining said exit opening and the wound, said protector including a pair of generally coaxial resilient rings contiguously connected to respective ends of a flexible tube, one of said rings being formed to compress said tube within said outer sleeve around said exit opening and the other of said rings adapted to compress said tube around the internal side of the wound.

- 12. 42. Apparatus according to claim
  41 wherein said tube is made of a supple
  material effectively impermeable to gases
  and microorganism-bearing fluids.
- 13. 43. Apparatus according to claim 42 wherein:

said tube is adapted to be in contiguous contact with the wound.

17. 44. Apparatus according to claim 32 wherein:

said second sealing means includes a pair of flanges interconnected on a common axis by a supple tube, said flanges being relatively adjustable about said axis for twisting said tube into a constricting position around an object.

18. 45. Apparatus according to claim 44 wherein:

said flanges include means for locking said flanges together in the constricting position.

# SUPPORT IN APPLICATION AND PCT PRIORITY DOCUMENT

Sealing diaphragm 62 extending between rings 61 and 63; Page 9, lines 30-33; Page 10, lines 1-4; Fig. 9.

Page 10, lines 2-4.

Page 10, lines 2-4; Sealing diaphragm 62 Fig. 9.

Rings 21 and 22 connected by sealing member 23; page 7, lines 20-33, Page 8, lines 1-28; Figs. 3-7.

Projections 27 and recesses 28; Page 8, lines 4-10 and lines 20-28; Figs. 3-7.

46. Apparatus according to claim32 wherein:

said second sealing means includes a first flange secured around said entry opening, a surgical glove for inserting into said outer sleeve through said first flange, and a second flange secured around the opening of said glove for sealing attachment to said first flange.

20. 47. Apparatus for use in handassisted minimally-invasive surgery in a sufflatable body cavity having an outer surface, comprising:

> an elongate flexible sleeve having an end portion adapted to be positioned adjacent the body cavity and a proximal end portion adapted to be positioned away from the body;

> means defining an exit opening laterally of said flexible sleeve adjacent to said distal end portion;

means defining an entry opening coaxially of said flexible sleeve at said proximal end portion;

first sealing means carried by said sleeve and surrounding said exit opening and adapted to engage said body outer surface;

second sealing means carried by said sleeve and surrounding said proximal end portion adapted to seal gastightly a surgeon's arm; and

means in said sleeve between its distal and proximal end portions providing a normally-closed flexible valve adapted to open upon insertion of the surgeon's hand toward the distal end portion of the sleeve and automatically close gastightly upon withdrawal of the surgeon's hand, said valve

# SUPPORT IN APPLICATION AND PCT PRIORITY DOCUMENT

First ring 51, second ring 52 and glove 53; Page 9, lines 20-26; Fig. 8.

Apparatus 1, 50, 60, 70; Page 1, lines 1-5; Page 7, lines 1-4; Page 9, lines 15-20; Page 10, lines 2-9; Figs. 1-4 and 8-10.

Sleeve 2, end 3 and open end 4; Page 7, lines 4-19; Figs. 1-4 and 9; sleeve 70, Page 10, lines 5-18; Fig. 10.

Exit opening 5, Page 7, lines 9-13; Figs. 1-4 and 9; Orifice 71 Page 10, lines 18-21.

Open end 4 Page 7, lines 5-9; Page 8, lines 14-20, Figs. 1-4.

Exit sealing means 10, Page 7, lines 14-19 Figs. 1-4, Ring 61, diaphragm 62 and ring 63, Page 9, lines 27-33; Page 10, lines 1-4 Fig. 9; Flange 72 Page 10, lines 21-23; Page 11, lines 3-8 Fig. 10.

Valve means 20, Page 7, lines 20-33, Page 8, lines 1-10, Figs. 3-7; First ring 51, second ring 52 and glove 53, Page 9, lines 20-26 Fig. 8; Circular members 76, 77 and tube 78 Fig. 10.

providing a third sealing means cooperable with said first sealing means to define a substantially gastight chamber in communication with said exit opening; Valve 74, Page 10, lines 10-13; Page 11, lines 12-17; Fig. 10.

whereby the surgeon can readily insert and withdraw the hand from the body cavity in the course of surgery without significant loss of pressure in the body cavity when sufflated.

- 48. Apparatus according to claim
  47 wherein said normally closed valve is of
  the duckbill type formed by at least one
  flexible panel secured to said sleeve and
  providing an aperture at a location adjacent
  to said exit opening.
- 24. 49. Apparatus according to claim 47 wherein said means defining an exit opening includes an annular flange having an adhesive coating adapted to secure the sleeve to the body outer surface with the sleeve extending alongside the body.
- 25. 50. Apparatus according to claim 47 including a flexible, tubular wound protector depending from said means providing said exit opening adapted to be inserted into a wound formed in said outer surface, said wound protector including a flexible membrane mounting annular elastic rings at opposite ends.
- 26. 51. Apparatus according to claim 47 wherein said proximal end second sealing means is adapted to engage gastightly the periphery of the surgeon's arm when the hand is inserted in the sleeve.

# SUPPORT IN APPLICATION AND PCT PRIORITY DOCUMENT

Page 10, lines 9-17.

Valve 74, Page 10, lines 10-13 and lines 23-26; Fig. 10.

Exit opening 5, Flange 11, 72, Page 7, lines 14-19; Page 8, lines 11-15; Page 11, lines 3-6; Figs. 1-4 and 10.

Sealing diaphragm 62 extending between rings 61 and 63; Page 9, lines 30-33; Page 10, lines 1-4; Fig. 10.

Circular members 76, 77 and tube 78; Page 10, lines 26-32; Page 11, lines 8-18; Fig. 10

27. 52. Apparatus for use in handassisted minimally invasive surgery in a gas sufflatable body, comprising:

> an elongate flexible having a lateral exit opening at one location and an axial entry opening at another location;

> first means adapted to seal gastightly said sleeve around said exit opening to a body surface undergoing minimally invasive surgery;

second means adapted to seal gastightly said sleeve around a surgeon's arm adjacent to said entry opening; and

means providing a duckbill check valve in said sleeve opening when said second sealing means is unsealed;

whereby a surgeon may insert and withdraw the hand through the exit opening without significantly affecting gas pressure in the sufflated body.

28. 53. Surgical apparatus for use in minimally invasive surgery for introducing a hand or instrument through a wound into an insufflated cavity comprising:

protective sleeve means of gasimpermeable material having a distal end adapted to be inserted through the wound for overlapping the lower edge thereof, and a proximal end formed to extend out of the wound;

an inside sealing ring, operatively connected to said sleeve means in proximity to the distal end, adapted to self-seal gastightly around the inside of the wound;

an outside sealing ring, operatively connected to said protective sleeve means in proximity end thereof and forming with said first sealing means a gastight chamber in said protective sleeve means and adapted to

# SUPPORT IN APPLICATION AND PCT PRIORITY DOCUMENT

Apparatus 1, 50, 60, 70; Page 1, lines 1-5; Page 7, lines 1-4; Page 9, lines 15-20; Page 10, lines 2-9; Figs. 1-4 and 8-10.

Sleeve 70, entry attachment device 76, 77, 78 and exit orifice 71; Page 10, lines 5-32; Fig. 10.

Annular flange 72, Page 10, lines 21-23; Page 11, lines 4-6; Fig. 10.

Entry attachment device 76, 77, 78; Page 10, lines 26-32; Page 11, lines 8-18; Fig. 10.

Valve 74, Page 10, lines 23-26; Page 11, lines 13-18; Fig. 10.

Page 11, lines 13-18.

Apparatus 60, Page 9, lines 27-29; Fig. 9.

Diaphragm 62 for insertion with ring 63 overlapping the lower edge of the wound; Page 9, lines 27-33; Page 10, lines 1-4; Fig. 9.

Inside ring 63, Page 9, lines 29-33 and Page 10, lines 1-4; Fig. 9.

Ring 61 connected to diaphragm 62, Page 9, lines 30-33; Page 10, lines 1-4, Fig. 9.

seal gastightly around the outside of the wound;

an elongate gas-impermeable supple sleeve extending laterally of said outside sealing ring; and

means providing a gastight-seal on said elongate sleeve at an end thereof remote from said outside sealing ring;

whereby the wound is protected by the protective sleeve while insufflation gas is contained within the elongate sleeve.

29. 54. Surgical apparatus according to claim 53 wherein:

said sleeve means includes a tubular portion closely conforming to the wound surface.

30. 55. Surgical apparatus according to claim 53 wherein:

said first sealing means includes a normally closed resilient member formed to prevent gas flow from the cavity into the chamber.

31. 56. Surgical apparatus according to claim 53 further comprising:

a resilient ring affixed around the distal end and adapted to expand beyond the edge of the wound when the distal end is fully inserted in the wound.

# SUPPORT IN APPLICATION AND PCT PRIORITY DOCUMENT

Sleeve 2, Page 2, lines 5-17, Page 7, lines 4-6, Fig. 9.

Valve means 20, Page 7, lines 20-33, Page 8, lines 1-10, Figs. 3-7; arm attachment device 76, 77, 78; Page 10, lines 26-32 Fig. 10.

Sealing diaphragm with protective sleeve or diaphragm 62. Page 9, lines 29-34; Page 10, lines 1-4, Fig. 9.

Diaphragm 62; Page 9, lines 29-34, Page 10, lines 1-4; Figs. 9.

Valve 74, Page 10, lines 10-13, Page 11, lines 12-17, Fig. 10.

Inside ring 63, Page 9, lines 29-33 and Page 10, lines 1-4, Fig. 9.

### APPENDIX B

## Count 1

Apparatus for use in minimally invasive surgery through a wound into an insufflated cavity comprising:

an outer sleeve of gas-impermeable supple material having an entry opening at a proximal end thereof and an exit opening at a distal end thereof;

first sealing means adapted to seal the exit opening gastightly around the wound in a patient, and

second sealing means adapted to seal the entry opening gastightly around a surgeon's arm received therein and create thereby a gastight chamber in said outer sleeve when a surgeon's arm is operatively received in said sleeve; whereby the sleeve cooperates with the first and second sealing means to enable the surgery to be performed under insufflatable conditions.

### Patentee's Claims

Applicant's Claims

1, 5, 6, 7, 8, 9, 10, 17, 18

5, 6, 8, 9, 10, 17, 25, 26, 28, 29, 32,

35, 36, 37, 38, 39, 40, 44, 45

## Count 2

Apparatus for use in minimally invasive surgery through a wound into an insufflated cavity, comprising:

an outer sleeve of gas-impermeable supple material having an entry opening at a proximal end thereof and an exit opening at a distal end thereof;

first sealing means adapted to seal the exit opening gastightly around the wound

of a patient;

second sealing means adapted to seal the entry opening gastightly around a surgeon's arm received therein and create thereby a gastight chamber in said outer sleeve when a surgeon's arm is operatively received in said sleeve; whereby the sleeve cooperates with the first and second sealing means to enable the surgery to be performed under insufflatable conditions; and

third sealing means interposed in said sleeve between said first and second sealing means adapted to maintain the gastight chamber with the wound when said second sealing means is breached.

Patentee's Claims

Applicant's Claims

2, 3, 20, 21, 24, 25, 26, 27

27, 30, 47, 48, 49, 50, 51, 52

#### Count 3

Surgical apparatus for use in minimally invasive surgery for introducing a hand or instrument through a wound into an insufflated cavity comprising:

protective sleeve means of gas-impermeable material having a distal end adapted to be inserted through the wound for overlapping the lower edge thereof, and a proximal end formed to extend out of the wound;

an inside sealing ring, operatively connected to said sleeve means in proximity to the distal end, adapted to self-seal gastightly around the inside of the wound;

an outside sealing ring, operatively connected to said protective sleeve means in proximity to the proximal end thereof and forming with said inside sealing ring a gastight chamber in said protective sleeve means and adapted to seal gastightly around the outside of the wound;

an elongate gas-impermeable supple sleeve extending laterally of said outside

sealing ring; and

means providing a gastight-seal on said elongate sleeve at an end thereof remote from said outside sealing ring; whereby the wound is protected by the protective sleeve while insufflation gas is contained within the elongate sleeve.

Patentee's Claims

Applicant's Claims

11, 12, 13, 28, 29, 30, 31

41, 42, 43, 53, 54, 55, 56

Count 4

Apparatus for use in surgery for receiving the hand of a surgeon to provide an entry to a patient's body through an incision made in the patient's skin comprising:

a sleeve having an entry opening at a first end thereof and an exit opening at a second end thereof spaced from the first end, said sleeve being formed to define an enclosed sleeve passage between said entry and exit openings,

exit sealing means formed on said sleeve to seal said sleeve at the exit opening to the patient's body around said incision, and

a glove assembly having an open end to permit passage into the glove assembly of a surgeon's hand, said glove assembly and sleeve being formed to permit attachment of said glove assembly to said sleeve to close and seal said sleeve passage in the area of said entry opening while permitting passage of a surgeon's hand in said glove assembly through the exit opening into a patient's body through the incision, said glove assembly being formed to receive a surgeon's hand and to extend over a surgeon's wrist and forearm.

Patentee's Claims

Applicant's Claims

19

31, 46, 57, 58, 59, 60, 61

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#### APPENDIX C - SUPPORT FOR COUNTS 1-4

- 1. Count 1 is patent claim 1 and applicants' claim 32 and support is shown in Appendix A and Appendix D.
- 2. Count 2 is patent claim 2 written in independent form and corresponds to applicants' claim 33. Support is shown in Appendix A.
- 3. Count 3 is patent claim 28 and corresponds to applicants' claim 53. Support is shown in Appendix A and Appendix D.
- 4. Count 4 is similar to patent claim 19 and corresponds to applicants' claim 57. Support is found in the U.S. and PCT applications as follows:

# 57. Apparatus for use in surgery for receiving the hand of a surgeon to provide an entry to a patient's body through an incision made in the patient's skin comprising:

a sleeve having an entry opening at a first end thereof and an exit opening at a second end thereof spaced from the first end, said sleeve being formed to define an enclosed sleeve passage between said entry and exit openings,

exit sealing means formed on said sleeve to seal said sleeve at the exit opening to the patient's body around said incision; and

a glove assembly having an open end to permit passage into the glove assembly of a surgeon's hand and forearm,

## SUPPORT IN APPLICATION AND PCT PRIORITY DOCUMENT

Apparatus 50 with entry opening 4 and exit opening 5, Page 1, lines 1-5, Page 7, lines 1-4; Figs. 1 and 3, Page 9, lines 15-21 Fig. 8.

Sleeve 2 with entry opening 4 and exit opening 5; Page 2, lines 5-17; Page 7, lines 4-13, Page 9, lines 15-21; Figs. 1-3 and 8.

Exit sealing means 10-11, Page 7, lines 14-19, Figs. 2, 3, 4, Page 8, lines 15-20 Fig. 8, Ring 61, diaphragm 62 and ring 63, Page 9, lines 27-33, Page 10, lines 1-4, Fig. 9.

Glove 53, Page 9, lines 20-26, Fig. 8.

said glove assembly and sleeve each being formed to permit attachment of said glove assembly in the area of the open end thereof to said sleeve in the area of said entry opening to close and seal said sleeve passage in the area of said entry opening while permitting passage of a surgeon's hand in said glove assembly through the exit opening into a patient's body through the incision,

Entry sealing means including the ring 51 mounted on the sleeve at the entry 4 and ring 52 at the free end of the glove 53, Page 9, lines 20-26, Fig. 8

said glove assembly being formed to receive a surgeon's hand and to extend over a surgeon's wrist and forearm. Glove 53, Page 9, lines 23-26, Fig. 8.

57. Apparatus for use in surgery for receiving the hand of a surgeon to provide an entry to a patient's body through an incision made in the patient's skin comprising:

SUPPORT IN IRISH PRIORITY DOCUMENT (930,649)

a sleeve having an entry opening at a first end thereof and an exit opening at a second end thereof spaced from the first end, said sleeve being formed to define an enclosed sleeve passage between said entry and exit openings, Apparatus 50 with entry opening 4 and exit opening 5, Page 6, lines 15-20; Figs. 1 and 8.

exit sealing means formed on said sleeve to seal said sleeve at the exit opening to the patient's body around said incision; and Sleeve 2 with entry opening 4 and exit opening 5; Page 4, lines 4-13; Figs. 1-3 and 8.

a glove assembly having an open end to permit passage into the glove assembly of a surgeon's hand and forearm, Exit sealing means 10-11, Page 4, lines 14-19, Figs. 2, 3, 4, Page 6, lines 15-26, Fig. 8.

Glove 53, Page 6, lines 20-26, Fig. 8.

said glove assembly and sleeve each being formed to permit attachment of said glove assembly in the area of the open end thereof to said sleeve in the area of said entry opening to close and seal said sleeve passage in the area of said entry opening while permitting passage of a surgeon's hand in said glove assembly through the exit opening into a patient's body through the incision,

said glove assembly being formed to receive a surgeon's hand and to extend over a surgeon's wrist and forearm.

Entry sealing means including the ring 51 mounted on the sleeve at the entry 4 and ring 52 at the free end of the glove 53, Page 6, lines 20-26, Fig. 8.

Glove 53, Page 6, lines 23-26, Fig. 8.

#### APPENDIX D - COPIED CLAIMS

#### PATENT CLAIM

1. 32. Apparatus for use in minimally invasive surgery through a wound into an insufflated cavity, comprising:

an outer sleeve of gas-impermeable supple material having an entry opening at a proximal end thereof and an exit opening at a distal end thereof;

first sealing means adapted to seal the exit opening gastightly around the wound in a patient; and

second sealing means adapted to seal the entry opening gastightly around a surgeon's arm received therein and create thereby a gastight chamber in said outer sleeve when a surgeon's arm is operatively received in said sleeve;

whereby the sleeve cooperates with the first and second sealing means to enable the surgery to be performed under insufflatable conditions.

5. 35. Apparatus according to claim 32 wherein:

said first sealing means includes a flexible flange secured around said exit opening and having an exposed face adapted to attach around the wound.

6. 36. Apparatus according to claim 35 further comprising:

an adhesive coating on said exposed face adapted to adhere to said flange around the wound.

7. 37. Apparatus according to claim 36 further comprising:

a peel-off strip covering said adhesive coating.

## SUPPORT IN IRISH PRIORITY DOCUMENT 930649

Page 1, lines 1-5; Apparatus 1; Figs. 1 and 3.

Page 4, lines 5-13; sleeve 2; Entry opening 4; Exit Opening 5; Figs. 1, 3, 9.

Exit sealing means 10-11 Page 4, lines 14-19; Figs. 1, 2, 3, 4; Ring 61, diaphragm 62 and inner ring 63 Page 6, lines 27-33, Page 7, lines 1-5 Fig. 9.

Valve means 20 Page 4, lines 20-33, Page 5, lines 1-10, Figs. 3-7; First ring 51, second ring 52 and glove 53, Page 6, lines 20-26 Fig. 8.

Page 5, lines 28-33.

Flange 11 Page 4, lines 14-19; Figs. 1-5; Page 5, lines 11-15.

Page 4, lines 14-19; Page 2, lines 1-5.

Peel off cover 12; Page 4, lines 18-19; Fig. 2, Page 2, lines 1-5.

#### PATENT CLAIM

8. 38. Apparatus according to claim 32 wherein:

said entry and exit openings are formed to accommodate a surgeon's hand and forearm.

9. 39. Apparatus according to claim 32 wherein:

said entry and exit openings are formed to accommodate instrumentarium.

10. 40. Apparatus according to claim 32 wherein:

said material is sufficiently flexible for effecting a wide range of arm movement at said entry opening relative to said exit opening.

11. 41. Apparatus according to claim 32 further comprising:

a wound protector means adapted to be inserted in the wound for simultaneously lining said exit opening and the wound, said protector including a pair of generally coaxial resilient rings contiguously connected to respective ends of a flexible tube, one of said rings being formed to compress said tube within said outer sleeve around said exit opening and the other of said rings adapted to compress said tube around the internal side of the wound.

- 12. 42. Apparatus according to claim
  41 wherein said tube is made of a supple
  material effectively impermeable to gases
  and microorganism-bearing fluids.
- 13. 43. Apparatus according to claim 42 wherein:

said tube is adapted to be in contiguous contact with the wound.

## SUPPORT IN IRISH PRIORITY DOCUMENT 930649

Page 4, lines 5; Page 5, lines 16-20; Fig. 4.

Page 7, lines 16-22.

Page 4, lines 4-5.

Sealing diaphragm 62 extending between rings 61 and 63; Page 6, lines 30-33; Page 7, lines 1-4; Fig. 9.

Page 6, lines 30-33; Page 7, lines 1-4.

Page 7, lines 2-4; Sealing diaphragm 62 Fig. 9.

#### PATENT CLAIM

17. 44. Apparatus according to claim 32 wherein:

said second sealing means includes a pair of flanges interconnected on a common axis by a supple tube, said flanges being relatively adjustable about said axis for twisting said tube into a constricting position around an object.

18. 45. Apparatus according to claim 44 wherein:

said flanges include means for locking said flanges together in the constricting position.

19. 46. Apparatus according to claim32 wherein:

said second sealing means includes a first flange secured around said entry opening, a surgical glove for inserting into said outer sleeve through said first flange, and a second flange secured around the opening of said glove for sealing attachment to said first flange.

28. Surgical apparatus for use in minimally invasive surgery for introducing a hand or instrument through a wound into an insufflated cavity comprising:

protective sleeve means of gasimpermeable material having a distal end adapted to be inserted through the wound for overlapping the lower edge thereof, and a proximal end formed to extend out of the wound;

an inside sealing ring, operatively connected to said sleeve means in proximity to the distal end, adapted to self-seal gastightly around the inside of the wound;

## SUPPORT IN IRISH PRIORITY DOCUMENT 930649

Rings 21 and 22 connected by sealing member 23; page 4, lines 20-33, Page 5, lines 1-28; Figs. 3-7.

Projections 27 and recesses 28; Page 5, lines 4-10 and lines 20-28; Figs. 3-7.

First ring 51, second ring 52 and glove 53; Page 6, lines 20-26; Fig. 8.

Apparatus 60, Page 6, lines 27-29; Fig. 9.

Diaphragm 62 for insertion with ring 63 overlapping the lower edge of the wound; Page 6, lines 27-33; Page 7, lines 1-4; Fig. 9.

Inside ring 63, Page 6, lines 29-33 and Page 7, lines 1-4; Fig. 9.

#### PATENT CLAIM

an outside sealing ring, operatively connected to said protective sleeve means in proximity end thereof and forming with said first sealing means a gastight chamber in said protective sleeve means and adapted to seal gastightly around the outside of the wound;

an elongate gas-impermeable supple sleeve extending laterally of said outside sealing ring; and

means providing a gastight-seal on said elongate sleeve at an end thereof remote from said outside sealing ring;

whereby the wound is protected by the protective sleeve while insufflation gas is contained within the elongate sleeve.

29. 54. Surgical apparatus according to claim 53 wherein:

said sleeve means includes a tubular portion closely conforming to the wound surface.

31. 56. Surgical apparatus according to claim 53 further comprising:

a resilient ring affixed around the distal end and adapted to expand beyond the edge of the wound when the distal end is fully inserted in the wound.

## SUPPORT IN IRISH PRIORITY DOCUMENT 930649

Ring 61 connected to diaphragm 62, Page 6, lines 30-33; Page 7, lines 1-4, Fig. 9.

Page 4, lines 4-6, Fig. 9.

Valve means 20, Page 4, lines 20-33, Page 5, lines 1-10, Figs. 3-7.

Sealing diaphragm with protective sleeve or diaphragm 62. Page 6, lines 29-34; Page 7, lines 1-4, Fig. 9.

Diaphragm 62; Page 6, lines 29-34, Page 7, lines 1-4; Figs. 9.

Inside ring 63, Page 6, lines 29-33 and Page 7, lines 1-4, Fig. 9.



PAPER NO. 12



## UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office

Address: BOX INTERFERENCE

COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

Telephone: (703) 308-9797 Facsimile: (703) 308-7952

MAILED

AUG 3 1 1998

PAT.8T.M. OFFICE BOARD OF PATENT APPEALS AND INTERFERENCES Applicants: Frank Bonadio and Alan Reido

Serial No. 08/641,811

Filed: 05/02/96

For: Apparatus Use in Surgery and a

Valve

Accorded Benefit Of: PCT International Application No. PCT/IE94/00043, filed 09/06/93, and Ireland Application Nos. 930,649, filed 09/06/93, and 930,650, filed

09/06/93

The case referred to above has been forwarded to the Board of Patent Appeals and Interferences because it is adjudged to interfere with other cases hereafter specified. Attention is directed to the fact that this interference is declared pursuant to 37 CFR § 1.601 et seq., effective February 11, 1985 (49 Fed. Reg. 48416, 1050 Pat. Off. Gaz. 385). The interference is designated as No. 104,195.

By direction of the Commissioner of Patents and Trademarks and as required by 35 U.S.C. § 135(c), notice is hereby given the parties of the requirement of the law for filing in the Patent and Trademark Office a copy of any agreement "in connection with or in contemplation of the termination of the interference."

The cases involved in this interference are:

### Junior Party

patrick F. Leahy, Berwyn M. Crook, and Patentees:

Robert D. Rambo

Derrynane #15, Glenart Avenue Address :

Blackrock, County Dublin, Ireland

921 Queens Drive Yardley, PA 19067

702 Simmons Road

Sellersville, PA 18960

Serial No.: 08/300,348, filed 09/02/94, now Patent No. 5,640,977,

issued 06/24/97

APPARATUS AND METHOD FOR USE IN SURGERY

Medical Creative Technologies, Inc. For: Assignee:

Attorneys of Record: Stanley B. Kita, George A. Smith, Jr.,
Wilson Oberdorfer, Mary E. Bak, Henry Hansen,

Cathy A. Kodroff, and William Bak

Accorded Benefit Of: Ireland Application No. S940,328, filed Associate Attorney: None

04/08/94

Stanley B. Kita Address:

Howson and Howson

Spring House Corporate Center

P.O. Box 457

Spring House, PA 19477

#### Senior Party

Applicants: Frank Bonadio and Alan Reid

Addresses: 2 Martello Terrace

Bray, County Wicklow, Ireland

7 Kincora Avenue

Clontarf, Dublin, Ireland

Serial No.: 08/641,811, filed 05/02/96

For: APPARATUS FOR USE IN SURGERY AND A VALVE

Assignee: None

Attorneys of Record: Daniel W. Sixbey, Gerald Joseph

Ferguson, Jr., Stuart Jay Friedman, Charles M. Leedom, Jr., David S. Safran, Joan K. Lawrence, Herman J. Hohauser, Donald R. Studebaker, and

Evan R. Smith

Associate Attorney: None

Accorded Benefit Of: PCT International Application No.

PCT/IE94/00043, filed 09/06/93; and Ireland Application Nos. 930,649, filed 09/06/93, and

930,650, filed 09/06/93

Address: Sixbey, Friedman, Leedom & Ferguson, P.C.

Suite 600

2010 Corporate Ridge McLean, VA 22102

#### Count 1

Apparatus for use in minimally invasive surgery through a wound into an insufflated cavity, comprising:

an outer sleeve of gas-impermeable supple material having an entry opening at a proximal end thereof and an exit opening at a distal end thereof;

first sealing means adapted to seal the exit opening gastightly around the wound in a patient; and

second sealing means adapted to seal the entry opening gastightly around a surgeon's arm received therein and create thereby a gastight chamber in said outer sleeve when a surgeon's arm is operatively received in said sleeve;

whereby the sleeve cooperates with the first and second sealing means to enable the surgery to be performed under insufflatable conditions.

The claims of the parties which correspond to this

count are:

Leahy et al.

: Claims 1-31

Bonadio et al.

: Claims 5, 6, 8-10, 17, 32-61

phn C. Martin

Administrative Patent Judge

(703) 308-9783

E

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

BONADIO et al.,	<b>)</b>	
Junior party JUN 2 0 2003	) ) Interference No. 104,195	ı
LEAHY et al.,	) Administrative Patent Jud ) John C. Martin	dge
Senior party	) BOX INTERFERENCE	<u>c</u>

#### JUNIOR PARTY'S RESPONSE TO NOTICE TO FILE OPENING BRIEF

Honorable Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

Please note that Junior Party Bonadio et al.'s does not intend to pursue any additional filings in the instant interference since it was unsuccessful in obtaining cooperation from its inventors. As a result, no further filings will be made by the Junior Party Bonadio et al. in the instant interference.

Respectfully submitted,

Jeffrey & Costellia Registration No. 35,483

NIXON PEABODY LLP 8180 Greensboro Drive, Suite 800 McLean, Virginia 22102 (703) 790-9110 (703) 883-0370 Fax

Counsel for Bonadio et al.

#### CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of RESPONSE TO JUNIOR PARTY'S NOTICE TO FILE OPENING BRIEF was served on counsel for the party Leahy et al. by facsimile and first class mail, properly addresses and postage prepaid, on July 10, 2001, as follows:

Stanley B. Kita, Esq. HOWSON & HOWSON One Spring House Corporate Ctr. P.O. Box 457 Spring House, PA 19477

Jeffrey L. Costellia



#### UNITED STATES PATENT AND TRADEMARK OFFICE BOARD OF PATENT APPEALS AND INTERFERENCES

ADDRESS: BOX INTERFERENCE JUN 2 0 2003

UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK DERICE

BONADIO FT AL (BONADIO

Junior Party,

LEAHY ET AL. (LEAHY),

Senior Party .

Interference No. 104,195 APJ: John C. Martin

Faxed to the parties, no copy will be mailed.

#### Show cause order

Pursuant to 37 CFR \$\$ 1.652 and 1.656(i), junior party Bonadio is hereby ordered to show cause within fifteen days why. as a result of Bonadio's failure to file a record or an opening brief, judgment on the issue of priority/derivation should not be entered against Bonadio's claims that correspond to the count and awarded in favor of Leahy's claims that correspond to the count.

dministrative Patent Judge (703) 308-9783 (direct)

GIVEN onder the common seal of ENCORET LIMITED.

Director

Director/Secretary

GIVEN under the common seal of ATROPOS LIMITED:

Director

Sue The Jos

Director/Secretary

#### Amended Schedule 1 to Assignment of Intellectual Property

#### **Dated 15 November 2002**

#### **Encoret Limited to Atropos Limited**

Patents or patent applications as follows:

Appln. No.	<b>Territory</b>	Appln, Date
USSN 08/513,985	United States	13 September 1995
USSN 08/641,811	United States	2 May 1996

**ENCORET LIMITED** 

Title: Director

Frank Bonadio Title: Director

In re A	Application of:		)
Bonac	lio et al.	i.	)
Applic	ation No.: 08/641,811		)
Filed:	May 2, 1996		)
For:	APPARATUS FOR US SURGERY AND A VAI		)
Mail S	top Petition		

Commissioner for Patents

Alexandria, VA 22313-1450

P.O. Box 1450

## DECLARATION OF MARTIN CALDWELL IN SUPPORT OF PETITION FOR REVIVAL UNDER 37 C.F.R. § 1.137(b) OF AN APPLICATION FOR PATENT UNINTENTIONALLY ABANDONED

- I, Martin Caldwell, declare as follows:
- 1. I am a Director of Encoret, Ltd. ("Encoret") and have been in this position from March 2, 1998 to the present.
- 2. I am making this Declaration in support of a Petition to Revive U.S. Patent Application Serial No. 08/641,811 ("the '811 application"), which petition I understand will be filed in the United States Patent and Trademark Office ("PTO").
- 3. As a Director of Encoret, I was authorized to make decisions regarding the prosecution of the '811 application before the PTO.
- 4. The '811 application was assigned to Encoret by one of the co-inventors, Frank Bonadio, on or about July 25, 1995. To the best of my knowledge and belief, a true copy of the assignment and related paperwork is attached as Exhibit A.

- 5. The other alleged co-inventor, Alan Reid, would not cooperate and refused to sign the patent application or assign his rights to Encoret. It is my understanding that despite Mr. Reid's refusal to sign, the '811 application was allowed to proceed to examination at the PTO. To the best of my knowledge and belief, a true copy of a Decision from the PTO acknowledging and accepting Mr. Reid's refusal to sign is attached as Exhibit B.
- 6. On or about December 16, 1997, Encoret requested that the PTO declare an interference between the '811 application and U.S. Patent No, 5,640,977 to Leahy et al. ("the Leahy patent"). To the best of my knowledge and belief, a true copy of the document requesting that interference be declared is attached as Exhibit C.
- 7. On or about August 31, 1998, the Board of Patent Appeals and Interferences ("the Board") at the PTO declared Interference No. 104,195 between the '811 application and the Leahy patent. To the best of my knowledge and belief, a true copy of the Declaration of Interference is attached as Exhibit D.
- 8. Mr. Bonadio (co-inventor) was a Director of Encoret from September 5, 1994 to on or about December 1998, when he resigned as a result of a dispute with Encoret. After his resignation, Mr. Bonadio had no further access to confidential company information, including information regarding the status of the '811 application.
- 9. As the result of Encoret's dispute with Mr. Bonadio and Mr. Reid's lack of cooperation, Encoret was unable to obtain the evidence it deemed necessary to proceed in the interference and, consequently, informed the Board in writing on or about

July 10, 2001, that the applicants did not intend to file further papers in the interference.

To the best of my knowledge and belief, a true copy of the paper filed notifying the

Board of Encoret's decision is attached as Exhibit E.

- 10. On or about July 19, 2001, the Board issued a Show Cause Order in the interference, requiring Encoret (i.e., the Junior Party Bonadio et al.) to respond within fifteen (15) days. To the best of my knowledge and belief, a true copy of the Show Cause Order is attached as Exhibit F.
- 11. Encoret was unable to respond to the Show Cause Order for the same reasons given above in paragraph 9; thereby resulting in termination of the interference.
- 12. To the best of my knowledge and belief, Encoret was not aware that the '811 application would go abandoned as a result of Encoret's decision regarding the interference, or that certain inventions disclosed in the '811 application, which were not part of the interference, could continue to be pursued separately in the '811 application after the interference was completed or in a continuation application.
- 13. Encoret did not intend for all of the inventions disclosed in the '811 application to go abandoned.
- 14. I have been informed that the PTO allegedly mailed a Notice of Abandonment for the '811 application on or about May 22, 2002. To the best of my knowledge and belief, Encoret never received notification of or a copy of that Notice (if at all) on or before the time that Encoret decided to assign the '811 application to Atropos Ltd. ("Atropos"), as indicated below.

- 15. To the best of my knowledge and belief, Encoret was not aware that the '811 application and all of the inventions disclosed therein went abandoned until on or about August 2002, when, in preparation for settlement discussions with Mr. Bonadio, Encoret was advised that the '811 application had been abandoned and could possibly be revived to pursue inventions that were not part of the interference.
- 16. At about that same time, however, the dispute between Encoret and Mr. Bonadio was being resolved, and ultimately settled. On or about November 2002, a settlement between Encoret and Mr. Bonadio resulted, in among other things, an assignment of Encoret's rights, title, and interest in and to the '811 application to Mr. Bonadio's new employer, Atropos. To the best of my knowledge and belief, a true copy of the assignment and an amended (corrected) assignment are attached as Exhibit G.
- 17. The entire delay from the date that the '811 application went abandoned until Encoret learned that it was abandoned on or about August 2002, was unintentional.
- 18. The entire delay from on or about August 2002 to November 2002, when Encoret's interests in the '811 application were assigned to Atropos, was a consequence of the settlement talks which occurred over a several-month period and was unintentional.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements

4

PATENT Customer No. 22,852 Attorney Docket No. 08203.0001

and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Dated: 16 June 03

Martin Caldwel

GIVEN under the common seal of ENCORET LIMITED: Director Director/Secretary

GIVEN under the common seal of ATROPOS LIMITED :

Director
Sue Tue
Director/Secretary

#### Amended Schedule 1 to Assignment of Intellectual Property

#### **Dated 15 November 2002**

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Date:  $\frac{9/4/03}{}$ 

ATROPOS LIMITED

Frank Bonadio
Title: Director

Date: